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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,363	02/18/98	MARK D	P97.1036

EXAMINER	
SHARAREH,S.	

ART UNIT	PAPER NUMBER
1616	13

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HILL & SIMPSON
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DATE MAILED: 06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/025,363	David Mark et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *12/3/99, 3/13/00*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, 4, 5, and 7-22* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 4, 5, and 7-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Status

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims 21-22 were omitted in previous Office Actions. Accordingly, the finality of a rejection is withdrawn in order to apply a new ground of rejection.

Claims 1-2, 4-5, 7-22 are now pending. Claims 3 and 6 have been cancelled.

Claim Rejections - 35 USC § 102

Claims 1-2, 4, 7-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl et al US Patent 5,504,072. Upon further review of Applicant's arguments filed in Paper no. 12, rejection of claim 5 has been withdrawn. Claims 21-22 are included in the instant rejection.

The instant claims are drawn to an enteral composition comprising a protein source comprising approximately 15%-20% of the calorie distribution of composition, wherein the protein source consist essentially of partially hydrolyzed protein, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-Carnitine source, wherein the composition having a caloric density of at least 1.4 Kcal/ml and provides a ratio of non-protein calories per gram nitrogen of about 140:1 to about 100:1. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube.

As discussed in Office Action, paper no. 4, Schmidl et al disclose suitable protein source including partially hydrolyzed protein (see col 4, lines 55-59.) Schmidl specifically disclose the use of partially hydrolyzed protein or intact protein as the source of protein (see col 11 lines 31-34.) Further Schmidl's composition provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11.) Applicant's arguments that Schmidl's composition has caloric density of 1 Kcal/ml; not 1.4, is not impressive, because the independent claim 1 of Schmidl's patent disclose an enteral nutritional composition comprising a 4-50% lipid component (a lipid source), a 65-80% carbohydrate component (a carbohydrate source), and a 16-25% protein component which can be a partially hydrolyzed protein such as whey (see col 11 lines 31-34, col 4 lines 55-60.) Schmidl et al also disclose that their composition provides a nonprotein calorie to grams of nitrogen ratio ranging from 150:1 to 80:1, thus, composition of Schmidl also inherently possess the instant claimed caloric density of 1.4 Kcal/ml, because it contains all the components of the independent claims 1 and 9. Further, Schmidl's teaching to dilute the composition to 1 kcal/ml is a preferred embodiment of their invention. Preferred embodiments do not constitute a teaching which is away from a broader disclosure or non preferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971). " A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley,* 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Schmidl also disclose the presence of free amino acid in their protein source at concentrations of 0.45%, and 1.03% for taurine and glycine respectively (see concentrations of glycine and taurine in col 9 lines 42-44), or 1-6% for arginine (see col 4 lines 65-67.) Thus, Schmidl meet the limitations set forth in claims 1-2, 4, 7-22.

Claim Rejections - 35 USC § 103

Claims 1-2, 4-5, 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072 and Gray et al 5,714,472.

Applicant's arguments have been fully considered. In response to Applicant's argument Examiner replies that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the instant case, Schmidl et al teach the desired NPC:N ratio for critically ill patients to be in the range of 150:1 to 80:1 (see col 5 lines 65-67 and col 6 lines 1-3.) further it is well known in the art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9.) Also the use of antioxidants, vitamins and various minerals is routine in nutrition art, and further Schmidl et al provide such teachings in their patent (see col 9 lines 45-66, col 10 lines 1-25.)

Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma in an intensive care setting, therefore, one skilled artisan would have been motivated to change the nonprotein calorie to grams of nitrogen ratio of Gray's composition to the desired ratios best fit for critically ill patients; as taught by Schmidl et al, and modify Gray's composition to formulate a product that suit the needs of metabolically stressed patients. Thus, claims 1-2, 4-5, 7-22 are rejected.

New Grounds of Rejection

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-5, 7-16, 21-22 rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al US Patent 5,221,668

The instant claims are drawn to an enteral composition comprising a protein source comprising approximately 15%-20% of the calorie distribution of composition, wherein the protein source consist essentially of partially hydrolyzed protein, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-Carnitine source, wherein the composition having a caloric density of at least 1.4 Kcal/ml and provides a ratio of non-protein

calories per gram nitrogen of about 140:1 to about 100:1. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube.

Henningfield et al disclose liquid nutritional products for trauma and surgery patient has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1, wherein a portion of protein system comprises partially hydrolyzed protein, and wherein 18-24% of the calories are provided by proteins, 20-30% are provided by lipids and 50-58% are provided by carbohydrates (see abstract table 1, col 6 lines 25-40, col 9 lines 1-68, claims 1, 4, 19 and 22.) The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22.) Thus, Henningfield meet the limitations set forth in the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 4-5, 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072.

The teachings of Schmidl et al were discussed above. Further, Schmidl et al also similar osmolality of about 630-690 mosm/kg of water (see col 7 lines 50-59.) and that their composition in the powder form has the caloric density of 4 cal/gram which can easily be diluted with an

aqueous liquid or juice to yield the caloric density of choice. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Thus, it would have been obvious to one ordinary skilled in the art to dilute the Schmidl's composition with appropriate amount of fluid to achieve the desired caloric density for critically ill patients who are fluid restricted, because he would have had a reasonable expectation to optimize the suitable range of caloric density that provides adequate fluid intake, by routine experimentation.

Generally, differences in concentration are not patentable unless applicant show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range (see MPEP 2144.05.)

4. Claims 1-2, 4-5, 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over and Henningfield et al US Patent 5,221,668 in view of Schmidl et al US Patent 5,504,072.

The instant claims are drawn to an enteral composition comprising a protein source comprising approximately 15%-20% of the calorie distribution of composition, wherein the protein source consist essentially of partially hydrolyzed protein, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-Carnitine source, wherein the composition having a caloric density of at least 1.4 Kcal/ml and provides a ratio of non-protein calories per gram nitrogen of about 140:1 to about 100:1. Further the instant claims encompass

methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube.

Henningfield et al teach liquid nutritional products for trauma and surgery patient has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1, wherein a portion of protein system comprises partially hydrolyzed protein, and wherein 18-24% of the calories are provided by proteins, 20-30% are provided by lipids and 50-58% are provided by carbohydrates (see abstract table 1, col 6 lines 25-40, col 9 lines 10-35, claims 1, 4, 19 and 22.) The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22.) Henningfield, however, fail to teach the use of partially hydrolyzed whey protein.

The teachings of Schmidl et al has been discussed above. Although, Henningfield does not teach the use of a partially hydrolyzed whey protein, he discuss the advantage of using partially hydrolyzed protein for better absorption. Schmidl has taught the use of partially hydrolyzed proteins in nutritional supplements for critically ill patients, therefore, it would have been obvious to one ordinary skilled in art to modify the hydrolyzed protein of Henningfield with a whey source, because an ordinary routine would have had a reasonable expectation to succeed in formulating a suitable nutritional product for fluid restricted patients that is easily absorbed.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose

telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400.

sjs 5/15/2000

S. Mark Clardy

S. MARK CLARDY
PATENT EXAMINER
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